RECEIVED
CENTRAL FAX CENTER
APR 11 2008

REMARKS

Claims 1-18 and 29-31 are pending in the application. Claims 1 and 17 have been amended. Support for all amendments and new claims can be found in the specification as originally filed. Applicants thank the Examiner for the indication of allowable subject matter.

REJECTIONS UNDER 35 USC 102(b)

Claims 1-4, 6 and 16-20 stand rejected under 35 USC 102(b) as being anticipated by Niehoff (hereinafter "Neihoff").

It is well settled that in order for a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in prior art. The disclosure requirement under 35 USC 102 presupposes knowledge of one skilled in art of claimed invention, but such presumed knowledge does not grant license to read into prior art reference teachings that are not there. See *Motorola Inc. v. Interdigital Technology Corp.* 43 USPQ2d 1481 (1997 CAFC). It is also well-settled that a 35 USC 102 rejection must rest upon the literal teachings of the reference and that the teachings must disclose every element of the claimed invention in as complete detail as is contained in the claim (See. *Jamesbury Corp v. Litton Industrial Products, Inc.* 225 USPQ, 253, 256 (CAFC 1985); *Kalman v. Kimberly-Clark Corp* 218 USPQ 781, 789 (Fed. Cir. 1983)).

The Office Action alleges that:

Niehoff teaches an injector system comprising:
A syringe (10), a plunger (12), an encoding device (physical indicia, see Claim 3): An injector (Fig 2B) with a housing (40), a motor (98), controller (160), a sensor to read the encoding device (detector, Claim 3), a drive member (20), the drive member operable to automatically advance after the syringe is mounted on the injector (Col 3 line 48 – Col 4 line 3); And a plunger engagement detection device (168).
As to claim 16, see potentiometer 168.

Claim 1 has been amended and is directed to an injector including "a plunger engagement detection device operably associated with the controller and operable to

indicate when a distal end of the drive member if the injector has engaged the plunger of the syringe." Niehoff, however, discloses an injector system that is completely different than Applicants' invention.

Niehoff is directed to an injection system that includes a CPU 52 that obtains feedback on an ongoing injection from sources. The sources include a linear potentiometer 168 physically coupled to the plunger 12 that indicates the position of the plunge. (See col. 9, lines 35-38 and col. 10, line 63-67). Using this information, the CPU 52 carefully controls the injection pressure, volume and speed. (See Col. 9, lines 37-40). Therefore, Niehoff discloses a potentiometer 168 that merely indicates the position of the plunger within the syringe during injecting, and there is no disclosure of any detecting when the unengaged plunger connects to the drive member. Therefore, Niehoff does not disclose "a plunger enegagement detection device ...operable to indicate when a distal end of the drive member of the injector has engaged the plunger," of Applicants' invention of Claim 1.

Regarding Claims 2 and 19, the Office Action alleges to: "see Col 1 line 65; "Before an empty new syringe can be filled, it is necessary that the plunger be moved fully forward in the syringe so that the syringe can be filled by rearward retraction of the plunger." Therfore, Neihoff does disclose that in an empty syringe a plunger must be "moved fully forward." However, Niehoff does not disclose any injector controller that determines from the encoding device a syringe is empty. Therefore, Niehoff does not disclose all the elements of Applicants' inventions of Claims 2 and 19.

Regarding Claims 3, 4 and 20, the Office Action alleges that, as to claim 3, 4, 20 see Col 3 lines 48-61: "To operate effectively, the plunger drive controller must determine the location of the plunger 12 relative to the ends of the syringe 10 ... offset value may be automatically computed by detecting physical indicia on the syringe." Therfore, Neihoff does disclose that the drive controller must determine the location of the plunger 21 relative to the ends of the syringe 10. However, Niehoff does not disclose any injector controller that determines from the encoding device a syringe is

prefilled and automatically stops the drive member upon engagement of the drive member of the plunger. Rather, Niehoff merely senses where the plunger drive jaw 20 which is coupled directly to and moves with the plunger 12. *Thus, the plunger drive jaw 20 is coupled, and therefore Niehoff does not disclose a controller to stop forward advancement of the drive member upon engagement because the jaw and plunder are already coupled. Therefore, Niehoff does not disclose all the elements of Applicants' inventions of Claims 3, 4 and 20.

Regarding Claim 16, Claim 16 has been amended and includes a sensor disposed on a distal end of the drive member or the plunger. Support can be found in the specification at page 14, lines 23-28 and in Fig.4B.

Further, regarding Claims 2-4, 6 and 16-18, Claims 2-4, 6 and 16-18 depend from Claim 1, which as already discussed is believed to be allowable. Reconsideration of Claims 1, 2-4, 6 and 16-20 is requested.

REJECTIONS UNDER 35 USC 103

Claims 7-15 and 21-28 stand rejected under 35 USC 103(a) as being unpatentable over Niehoff and in view of Bucchianeri. This rejection should be withdrawn in view of the remarks made herein.

The Office Action alleges that:

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the light source/sensor of Bucchianeri with the injector syringe system of Niehoff in order to prevent de-coupling of the syringe/driver and injection error. Regarding the limitation that the sensor is on the plunger (claim 11), this would have been obvious to one of ordinary skill in the art since it would involve the mere reversal of the parts.

It is well settled that to establish a *prima facie* case of obviousness, the USPTO must satisfy all of the following requirements. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to

modify a reference or to combine references. *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Second, the proposed modification does not have a reasonable expectation of success, as determined from the vantage point of one of ordinary skill in the art at the time the invention was made. *Amgen v. Chugai Pharmaceutical Co.* 18 USPQ 2d 1016, 1023 (Fed Cir, 1991), *cert. denied* 502 U.S. 856 (1991). Third, the prior art reference or combination of references must teach or suggest all of the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496, (CCPA 1970).

However, Neihoff does not disclose "a linear potentiometer that indicates when the drive member has progressed far enough to engage the plunger..." as alleged in the Office Action. Rather Niehoff discloses that the linear potentiometer 168 provides feedback on the postion of the plunger inside of the syringe (col. 9, lines 35-37) during an ongoing injection. (See col. 9, lines 27-28). This is after the plunger drive jaw 20 is coupled to and moves with the plunger 12. Therefore, Niehoff is directed to a potentiometer that measures after engagement of the the drive and plunger, and during the injecting of fluid. Accordingly, Niehoff does not disclose Applicants' invention including "a plunger engagement device operably associated with the controller and operable to indicate when a distal end of the drive member of the injector has engaged the plunger of the syringe."

Further, Bacchianneri does not remedy the deficiencies of Niehoff. In fact, Bacchianneri teaches away from Applicants' invention of Claims 7, 21 and 25. Bacchianneri is directed to a light sensor 28a disposed on a traveler mechanism 19 located radially below the plunger. This is completely different than Applicants' invention and can not be combined with the teaching of Niehoff, because Niehoff requires plunger drive that includes a jaw 18 designed to engage a button 14 on the plunger 12 (or extender 16). (see Col. 1, line 62-63 and Fig.'s 1A and 1B). Bacchianneri , on the other hand, connects the plunger 11b via a crank arm 17. Further, Bacchianneri teaches the sensor 28a located axial below the connection of the crank arm 17 and plunger 11b. Neihoff, however, requires a drive member to

axially abut the proximal end of the plunger. Accordingly, Neihoff and Bacchianneri can not be combined to each or suggest Applicant's invention. And, contrary to the allegation in the Offcie Action "the plunger and drive member system of Niehoff includes structural features which would allow a light sensor/ source combination to function without altering the structures of the coupling," Niehoff can not be combined with Bacchianneri to arrive at Applicants' invention, including any reversing of parts to arrive at Claim 11. In fact, reversal of the parts in view of the combination of Niehoff and Bacchianneri would not yield an operable invention.

Regarding Claims 8-15 and 22-24 and 26-28, Claims 8-15 and 22-24, 26- 28 depend from Claims 7, 21 and 25, respectively, which as discussed are believed to be allowable. Accordingly, Claims 8-15 and 22-24 and 26-28 are believed to be allowable, and reconsideration Is requested.

CLAIM OBJECTIONS

Claims 17 and 18 are objected to under 37 CFR 1.75(c) as being improper dependent form for failing to limited the subject matter of a previous claim. In light of the amendments and comments below, reconsideration is requested.

Regarding Claim 17, Claim 17 has been amended and further limits the sensor as disclosed in Claim 1, from which it depends. The further limitation of "the sensor is adapted to read the encoded syringe information when the syringe is mounted on the injector" is not recited in Claim 1, accordingly reconsideration is requested.

Regarding Claim 18, Claim 18 includes a further limitation of the drive member automatically advancing and engaging the plunger, namely, "when the sensor reads the syringe information encoded on the syringe," which is not recited in Claim 1, accordingly reconsideration is requested.

DOUBLE PATENTING

Claims 19-27 are objected to under 37 CFR 1.75 as being substantial duplicates of Claims 2, 3, 7-9 and 11-15. Claims 19-28 have been canceled.

NEW CLAIM

Claim 31 has been added. Support for the claim is found in the specification as

filed at page14, lines 23-25 or page 15, lines 1-8 and in Figures 4a, 4b and 4e. Consideration is respectfully requested as the cited art does not teach or suggest this limitation.

In view of the above amendments and remarks, Applicants submit that the claims are in condition for allowance and the Examiner would be justified in allowing them.

Respectfully submitted,

Date: April 10, 2008

By _____
Jill Denesvich
Attorney for Applicants
Registration No. 52,810